REMARKS

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks herein, is respectfully requested. Claims 1-2, 4-9, 20-26, 29-30, 32, and 39 are pending in this application.

At page 2 of the Office Action, the Examiner indicates that a complete reply to the final rejection must include cancellation of nonelected claims, i.e., claims 9, 20-26, 29-30, and 32. The Office Action dated December 26, 2007 is a non-final Office Action (see PTOL-326 included with the Office Action). Moreover, in the Response to Restriction Requirement mailed on July 31, 2006, Applicant requested rejoinder of the method claims, e.g., claims 21-26, with the elected composition of matter claims. Thus, it is Applicant's position that cancellation of any of the nonelected claims is not appropriate at this time.

The Examiner asserts that claim 39 is directed to an invention that is independent and distinct from the elected invention in that it recites SEQ ID NO:27 which is different than SEQ ID NO:26. The Examiner is requested to consider that the elected invention (see the Response to Restriction Requirement mailed on July 31, 2006) is directed to a cholesterol recognition/interaction amino acid consensus sequence comprising $Z\text{-}(X)_{0\text{-}5}\text{-}Y\text{-}(X)_{0\text{-}5}\text{-}Q$ (SEQ ID NO:26), wherein Z is a neutral hydrophobic amino acid, Y is a neutral polar amino acid, Q is a basic amino acid and X is any amino acid, and that claim 39 is directed to a peptide having a cholesterol recognition/interaction amino acid consensus sequence, wherein the peptide consists of $(X)_{0\text{-}4}\text{-}Z\text{-}(X)_{0\text{-}5}\text{-Tyr-}(X)_{0\text{-}5}\text{-}B\text{-}(X)_{0\text{-}5}$ (SEQ ID NO:27) wherein Z is leucine or valine (neutral hydrophobic amino acids), B is arginine or lysine (basic amino acids) and X is any amino acid. Therefore, claim 39 is directed to the elected invention.

Claims 1-2, 4-8 and 20 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and enablement. These rejections are respectfully traversed.

In particular, with regard to written description, the Examiner asserts that the claims do not disclose any identifying structural characteristics associated with functional activity, and there is no description of conserved regions or the sites at which variability may be tolerated.

The Examiner is requested to consider that the claims and specification clearly indicate conserved regions, i.e., the tyrosine residue, the neutral hydrophobic amino acid Z and the basic amino acid B in $Z\text{-}(X)_{0\text{-}5}\text{-Tyr-}(X)_{0\text{-}5}\text{-}B$. Moreover, the sites at which variability may be tolerated

are also clearly indicated, i.e., $(X)_{0-5}$ wherein X is any amino acid. And with respect to structural characteristics associated function, claim 1 recites that $Z-(X)_{0-5}$-Tyr-$(X)_{0-5}$-B (structure) is a cholesterol recognition/interaction (function) amino acid consensus sequence.

Therefore, the claims satisfy the written description requirement of § 112(1).

With regard to enablement, the Examiner asserts that it would require undue experimentation by one of skill in the art to make/use the cholesterol recognition/interaction amino acid consensus sequence consisting of SEQ ID NO:26, and that the claims totally lack enablement because it is not predictable that the peptide consisting of SEQ ID NO:26 is a cholesterol recognition/interaction amino acid consensus sequence.

As acknowledged by the Examiner, the specification teaches the minimum amino acid sequence specific for recognition/interaction with cholesterol (page 8 of the Office Action). Moreover, the specification discloses that the consensus sequence may be employed to block or compete for binding or in fusion polypeptides. It is Applicant's position that it is well within the skill of the art to prepare recombinant peptides or polypeptides having the consensus sequence. Moreover, if a manner of using a claimed invention is available to one of ordinary skill in the art, the "how to use" requirement of 35 U.S.C. § 112(1), has been satisfied. In re Nelson, 126 U.S.P.Q. 242 (C.C.P.A. 1960).

It is established law with respect to enablement that the specification must be taken as being in compliance with the first paragraph of 35 U.S.C. § 112 unless there is reason to doubt the objective role of the statements contained in the specification which must be relied upon for enabling support. In re Marzocchi, 169 U.S.P.Q. 367 (C.C.P.A. 1971). The Examiner has not provided objective evidence to doubt the assertion that the cholesterol recognition/interaction amino acid consensus sequence, either alone or in the context of other sequences so as to form a mutant polypeptide or a fusion polypeptide, is capable of interacting or recognizing cholesterol. In this regard, the Examiner is requested to consider Li et al. (Proc. Natl. Acad. Sci. USA, 98:1267 (2001)) (a copy is enclosed herewith) which disclose the inhibition of steroidogenesis by an HIV TAT-cholesterol recognition/ interaction amino acid consensus peptide, and Wang et al. (J. Biol. Chem., 283:8034 (2008)) (a copy is enclosed herewith) which disclose that a sterol binding domain of OSBP is functional whether attached to the N- or the C-terminal half of OSBP.

If Applicant's invention is disclosed so that one of ordinary skill in the art can practice the claimed invention, even if the practice of the invention by the art worker includes routine screening or some experimentation, Applicant has complied with the requirements of 35 U.S.C. § 112, first paragraph. In re Angstadt, 190 U.S.P.Q. 214 (C.C.P.A. 1976); Ex parte Jackson, 217 U.S.P.Q. 804 (Bd. App. 1982).

Moreover, the Federal Circuit has explicitly recognized that the need, and methodologies required, to carry out extensive synthesis and screening programs to locate biomolecules with particular properties do not constitute undue experimentation. In re Wands, 8 U.S.P.Q.2d 1400, 1406-1407 (Fed. Cir. 1988), the Court stated:

> The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody.

Likewise, practitioners in the art related to the present application would be well-equipped to prepare and screen peptides with amino acid sequences within the scope of claim 1 to identify those with cholesterol recognition/interaction amino acid sequences. See also, Hybritech Inc. v. Monoclonal Antibodies Inc., 231 U.S.P.Q. 81, 84 (Fed. Cir. 1986) (evidence that screening methods used to identify characteristics [of monoclonal antibodies] were available to art convincing of enablement). Evidence that it is within the skill of the art to prepare and screen peptide libraries is provided in the abstract for Cheng et al., Proc. Natl. Acad. Sci. USA, 94:14120 (1997); Apletalina et al., J. Biol. Chem., 273:26589 (1998); and He et al., J. Gen. Virol., 79:3145 (1998) (of record; a copy of each was enclosed with the Amendment filed on October 1, 2007). The Examiner has failed to consider this evidence, as required by M.P.E.P. 2164.05.

Therefore, the specification enables the claimed invention.

Thus, withdrawal of the § 112(1) enablement rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date Jun 26, 2008 By _____
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Attn-Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 26th day of June, 2008.

Amy Moriarty
Name

_____
Signature